EXHIBIT E

Neutral Citation No. [2007] IEHC 256

THE HIGH COURT

[2004 No. 18683 P]

BETWEEN

**RANBAXY LABORATORIES LIMITED,
RANBAXY EUROPE LIMITED AND
RANBAXY IRELAND LIMITED**

PLAINTIFFS

**AND
WARNER-LAMBERT COMPANY**

DEFENDANT

Judgment of Mr. Justice Clarke delivered on the 10th July, 2007.

1. Introduction

1.1 The search for drugs effective against cholesterol has intensified in recent years. In the middle 1980's a number of break throughs occurred. By May, 1986, a class of compounds known as "statins" was recognised as being of potential application for cholesterol lowering medicines. In particular natural products such as mevinolin and compactin were recognised as potentially key. In that context the defendant ("Warner-Lambert") developed a synthetic compound which was patented in very many jurisdictions including Ireland. The plaintiffs ("Ranbaxy") now seeks a declaration, under s. 54 of the Patent Act 1992 ("the Act"), that the manufacture and/or import and/or sale of a compound called atorvastatin calcium in Ireland would not infringe Warner-Lambert's Irish patent. While there are other proceedings between the parties concerning the validity of that patent, no such challenge is brought in these proceedings. Therefore the net question that arises concerns whether Ranbaxy's "atorvastatin calcium" infringes Warner-Lambert's Irish Patent No. 60014.

1.2 That patent was granted for an invention entitled *"Trans- [2-(3-or 4-carboxamido-substituted pyrrol-1-yl) alkyl]-4- hydroxpyran-2-one inhibitors of cholesterol synthesis".* In order to understand the dispute between the parties it will be necessary to turn, in early course, to the underlying chemistry behind both the patent and Ranbaxy's competing product. However, as will become clear, the key issue in the dispute concerns the proper interpretation of Warner-Lambert's Irish patent. Ranbaxy argues that, properly construed, that patent relates only to what are described as "racemic mixtures" and that its competing product is not a racemic mixture. Warner-Lambert argues that a proper construction of its Irish patent covers a wider range of molecules. The true net issue between the parties is, therefore, as to the proper construction of Warner-Lambert's Irish patent. If it is to be construed in the way contended for by Warner-Lambert then it follows that it is wide enough to cover Ranbaxy's competing product. If, on the other hand, it is, properly construed, to be given the narrower interpretation contended for on the behalf of Ranbaxy then it is equally clear that the competing product produced by Ranbaxy is not covered. The real issue, therefore, concerns the construction of the Irish patent.

1.3 Finally, before turning to the underlying chemistry necessary to understand and, therefore, construe the patent it should be noted that the same or similar disputes exist between the parties to these proceedings, or other appropriate corporate entities associated with them, in a whole range of other jurisdictions. A number of those disputes have been the subject of judicial determination and it will be necessary to refer to the relevant litigation in due course. However it is first appropriate to turn to the underlying chemistry.

2. Stereochemistry

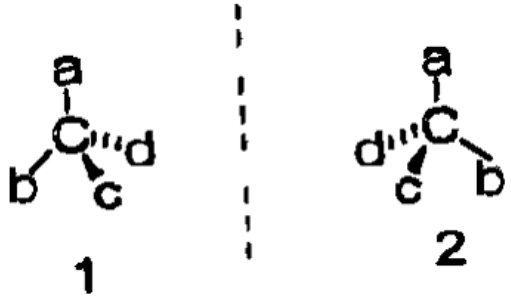
2.1 Stereo chemistry is the study of the three dimensional structure of molecules. Many will recollect from their school days the basic underlying structure of molecules being comprised of a number of atoms. Basic chemical formulae represent a molecule by describing the types and number of atoms involved. At a slightly more complex level isomers are compounds that have the same number and type of atoms but where the atoms are arranged in a different manner.

2.2 One particular type of isomer is termed a stereoisomer. The differences between stereoisomers exist in three dimensions. This leads to a consideration of how the three dimensional structure of certain molecules are, by convention, depicted in written form.

2.3 Again chemical formulae can be written as a continuous series of letters depicting particular atoms and appropriate numbers representing the number of atoms in the molecule concerned. Alternatively the composition of a molecule can be shown in a pictorial fashion setting out, in a two dimensional way on the page, the way in which the relevant atoms are arranged. By convention a dash is used to represent bonds between atoms in the plane of the page, a wedge is applied for bonds coming upwards out of the plane of the page and a broken or hashed line is used for bonds that go behind or down from the page.

2.4 These conventions are important to the issues which arise in this case because the patent (as will indeed be the case with any chemical patent) is represented in written form. It is the proper interpretation of that written form which, therefore, lies at the heart of the dispute between the parties in this case.

2.5 The carbon atom (along with hydrogen and oxygen) forms the basis of organic chemistry. A carbon atom is capable of bonding with four other atoms or groups of atoms in a way which, in three dimensional terms, resembles a tetrahedron. The representation below shows two different three dimensional representations of such a tetrahedron. In each case the centre is a Carbon atom. It will also be noted that in each case four different other atoms or groups of atoms numbered respectively a, b, c, d, are attached. From the notation referred to above, the "c" atoms (being represented by a wedge) should be visualised as being above the page while the "d" atoms (being represented by a hashed line) should be seen as being below the page. The a and b atoms (being attached by a dash) should be seen as being in the plane of the page. In any of the relevant cases what is attached to the carbon atom may also be a group of atoms rather than a single atom. It will also be seen that the two molecules (1 and 2) represented are mirror images of each other and are not capable of being superimposed one on the other. Any physical object (such as the two hands of a human being) whose mirror image is not identical with itself is said to be chiral. Where stereoisomers exist that are not superimposable mirror images of each other they are known as enantiomers. Therefore enantiomers will be made up of the same atoms arranged in almost the same way save that they are mirror images of each other in the way depicted.



2.6 It has been well known for some time that despite their chemical similarity enantiomers often have very distinct properties. The tragic case of

thalidomide is often put forward as one of the best known examples. One enantiomer in that case was an effective sedative. Unfortunately the other enantiomer caused serious birth defects. Regrettably the adverse effects of the latter enantiomer were not discovered until after many tragic cases had occurred.

2.7 There would appear to be a number of different conventions used for the purposes of distinguishing between different enantiomers of the same compound. One such convention relies upon the fact that enantiomers typically rotate plane polarised light in either a clockwise or anticlockwise direction depending on which enantiomer is involved. Using this notation the enantiomer which rotates plane polarised light in a clockwise direction is labelled "+" or "d" (the latter being for dextrorotatory). The enantiomer which rotates polarised light in an anti-clockwise fashion is labelled "-" or "l" for levorotary. This leads to the definition at the heart of the chemistry involved in the compounds with which I am concerned. A racemic mixture (or racemate) is a mixture of two enantiomers which is, for all practical intents and purposes, equal. It is frequently labelled "±". It will not, in fact, rotate plain polarised light at all since the effect of the two constituent enantiomers cancel each other out.

2.8 An alternative means of distinguishing, in written form, different enantiomers stems from a naming system known as the Cahn-Ingold-Prelog system of nomenclature which provides for priority rules. Under these rules the different atoms attached to the carbon centre are ranked in accordance with their atomic number. If this ranking gives rise to a clockwise arrangement then the enantiomer is called R (from the Latin "rectus"). If the appropriately ranked arrangement gives rise to a counter-clockwise order then it is termed S (from the Latin "sinister").

2.9 The reason why a racemic mixture or racemate will arise in practice in many cases is that the chemical process leading to the production of the compound is likely to result in the production of an R enantiomer or an S enantiomer on a random basis depending on the way in which the atoms come together in the course of the chemical reaction concerned. On that basis, to all practical intents and purposes, the amount of R and S enantiomers in the compound will be equal. That compound is, therefore, termed a racemic mixture or racemate.

2.10 Where a molecule has two chiral centres there are, therefore, four (that is two by two) possible isomers. The convention for naming in such cases requires the identification of whether what are described as the substituents lie on the same or opposite sides of the plane of reference. If they lie on the same side the arrangement is called a "cis" arrangement. Where the substituents appear on opposite sides of the plane the arrangement is, not surprisingly, called a "trans" arrangement. As will be seen the compounds with which I am concerned in these proceedings involve two chiral centres and thus there are four possible isomers. There are a number of ways by which, by convention, each of the four such possibilities may be described. However, for convenience, I propose mainly to refer to the four possibilities as respectively the R-trans, R-cis, S-trans and S-cis. As will again be seen the patent in this case expressly excludes the two cis isomers. It is, therefore, confined to the R-trans and S-trans.

2.11 As I have indicated earlier a compound of equal amounts of those two enantiomers is described as a racemate or racemic mixture. As will become clear, the issue in this case is as to whether the manner in which the claims are made in the patent under consideration, properly construed, gives rise to a patent in the racemic mixture only (as is contended for on the part of Ranbaxy) or gives rise to a patent in not only the racemic mixture but also the two individual R-trans and S-trans enantiomers and, indeed, any other mixture, (that is to say, a mixture which is not divided as to 50% one and 50% the other and is not, therefore, a racemic mixture) of those two enantiomers (as is argued for on behalf or Warner-Lambert).

2.12 That is the net question which arises. Against that general background it is, therefore, necessary to turn to the legal principles applicable to the construction of a patent.

3. The principles of construction

3.1 Subject to one issue of substance which emerged in the course of the hearing (and which had not, quite frankly, been apparent to any great extent in the written submissions filed prior to the hearing) the legal principles applicable to the construction of a patent were not the subject of significant dispute between the parties.

3.2 It is important to remember what the purpose of a patent is. It is to confer upon the successful applicant for a patent a monopoly, for the duration of the patent, on the invention which is the subject of the patent itself. As pointed out by Lord Hoffman in *Kirin-Amgen v. Hoechst* [2005] RPC 9 the boundary of the monopoly is a matter of considerable importance to all concerned. Lord Hoffman stated (at p. 21) that:-

> "The need to set clear limits upon the monopoly is not only, as Lord Russell emphasised, in the interests of others who need to know the area "within which they would be trespassers", but also in the interests of the patentee, who needs to be able to make it clear that he lays no claim to prior art or insufficiently enabled products or processes which would invalidate the patent."

3.3 That statement emphasises one of the key balancing factors that is involved in any patent application. On one side a patentee might well be regarded as wishing to obtain as wide a patent as he possibly can, for that will extend the boundary of his monopoly to the widest possible area. On the other hand an excessively wide patent application may, of course, fail because it may seek to include, within the patent claimed, elements of the so called "prior art", that is matters that were already known at the time of the patent application, or may otherwise cause the patent to be invalid.

3.4 Section 45(1) of the Act provides that the extent of the protection conferred by a patent is to be determined by the terms of the claims as interpreted by the description and any drawings. Section 45(3) provides that the protocol on the interpretation of article 69 of the European Patent Convention ("EPC") (which corresponds to s. 45(1)) shall apply for the purposes of s. 45(1) as it does for article 69.

3.5 Article 69 of the EPC is in the following terms:-

> "Article 69 should not be interpreted in the sense that the extent of the protection conferred by a European patent is to be understood as that defined when a strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purposes of resolving an ambiguity found in the claim. Neither should it be interpreted in the sense that the claims serve only as a guideline and that the actual protection conferred may extent to what, from a consideration of the description and drawings by a person skilled in the art, the patentee has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patentee with a reasonable degree of certainty for third parties."

3.6 A number of the learned commentaries on the protocol suggest that it is designed to steer a middle course between what might have been regarded as the historical literal common law approach to a patent on the one hand and the German approach, which involved a very generalised approach to construction of the entire document, on the other hand.

3.7 The protocol needs to be seen in the context of the fact that, typically, a patent document will set out in specific terms the claims made. It will also set out, by way of examples, descriptions and the like, further detailed specifications which will allow an understanding of the matters in respect of which the claims are made and will afford persons interested in the area a much greater understanding of the advance in knowledge which is said to form the basis of the invention at the heart of the patent itself. It does, of course, need to be recalled that the underlying basis for the grant of a patent at all is that the patentee obtains his monopoly in return for disclosing to the public generally (and, perhaps, the relevant sector of the scientific community in particular), the advance in scientific or technical knowledge that is claimed to be inventive.

3.8 As will be seen, the protocol requires a departure from an overly literal approach to the construction, in a semantic way, of the terms of the claims. The balance of the patent document is not only to be used for the purposes of resolving any ambiguity in the claims but also can properly be taken into account in construing the patent document as a whole for the purposes of determining the extent of the claims.

3.9 The other key concept involved in the construction of the patent is that it must be approached from the standpoint of what has been described in the authorities as the "skilled addressee". The skilled addressee is taken to be a person or persons with practical knowledge and experience of the kind of work in which the invention was intended to be used: see *Catnic Components Ltd v. Hill and Smith Ltd* [1982] RPC 183 at 242-243. It is common case that I should attempt to read the patent and construe it in the way in which the so called skilled addressee would have done so.

3.10 The knowledge which will be attributed to the notional skilled addressee is the knowledge that any worker in the area concerned would be expected to have as part of their general knowledge. See for example *General Tyre v. Firestone Tyre* [1972] RPC 457 at 482. The knowledge is that which a skilled addressee would have had as of the "priority date" which, for the purposes of this patent, it is common case, is the 30th May, 1986. It is, therefore, agreed between the parties that I should approach the construction of this patent on the basis of the common general knowledge that would have been available to a person working in the field (of which more later) as of that date. It is important in that context to define the role of expert witnesses. Both sides called such evidence. On behalf of Ranbaxy, evidence was led from Professor Derek Clive who is Professor of Chemistry in the Department of Chemistry, Gunning Lemieux Chemistry Centre at the University of Alberta. Warner-Lambert led evidence from Dr. Rodger Newton who had extensive experience as a research chemist eventually becoming Director of the Chemical Research Division of Glaxo group and currently holds a number of academic and consultancy positions. Warner-Lambert also led evidence from Professor Hegarty who is Professor of Organic Chemistry at University College, Dublin.

3.11 The role of that expert evidence needs to be clearly defined. It is common case that it is not the function of experts, in proceedings such as this, to offer a view as to the proper construction of the patent. Rather it is the function of such experts to enable the court to understand (and if necessary, in the case of dispute, to determine) the common general knowledge which would have been available to a skilled addressee as of the priority date. See for example *Lubrizol v. Esso Petroleum* [1998] RPC 727 at 738.

3.12 There is a slight difference of some marginal materiality in the relative expertise of the two principal experts called. This is not to distinguish the level of their expertise but rather to identify the precise focus of that expertise. Professor Clive describes himself as a "synthetic organic chemist who specialises in the synthesis of complex molecules with important medicinal properties". On the other hand Dr. Newton describes himself as a medicinal chemist. Dr. Newton defines medicinal chemistry as being concerned with the search for chemical compounds that can help to solve biological problems of clinical importance to mankind. Thus, there may be little practical difference, for most purposes, between the professional focus of both experts. However, insofar as there is a difference it does seem to me to stem from the fact that Dr. Newton has an expertise which was particularly focused on the production of actual medicines. As became clear in the course of the evidence there are a great number of practical steps which may have to be taken between the identification of a chemical compound which may be seen to have beneficial effects, for persons who might be treated with it, on the one hand, and the development of a practical means of being in a position to treat patients with that compound in an effective manner. While the detail of such matters is of no relevance to these proceedings, Dr. Newton made the point that the practical application of a compound required that it be capable of being produced in a stable form in an appropriate way (such as a tablet, injection or the like) which can be used for the effective treatment of patients. Insofar as there may have been a slight difference in the areas of expertise of the two experts, it seems to me that Dr. Newton, by reason of his professional experience as a medicinal chemist employed in industry, had an additional focus on those aspects of the search for effective treatments which were concerned not only with identifying the appropriate compounds that might be of beneficial use but also of considering how those compounds might be capable of being effectively used in practice.

3.13 There is clearly a very large overlap indeed between the two areas of expertise. Insofar as there may be a slight difference between the two, I am satisfied that the skilled addressee is, to a significant extent, a combination of both. The notional skilled person is one who has practical knowledge and experience of the kind of work in which the invention was intended to be used. The invention is intended to be used in relation to the making of chemical compounds useful in the reduction of cholesterol. That involves persons such as Professor Clive, who are synthetic organic chemists, and also persons such as Dr. Newton who are medicinal chemists. I will go on to deal (at para. 5.21) with one aspect of the construction of the patent on which, for the reasons which I will then set out, I am satisfied that Dr. Newton's perspective is particularly relevant. Lord Diplock in *Catnic* described the skilled addressee as a person "with practical knowledge and experience of the kind of work in which the invention was intended to be used". To the extent, therefore, that a patent is intended as a practical invention, the emphasis, in the skills to be attributed to the notional addressee, is on the practical skills which would be required to make use of the invention.

3.14 The one area where an issue of difference arose between counsel as to the proper approach to be adopted in the construction of a patent such as that with which I am concerned relates to the question of whether a consideration such as the "business efficacy" approach to the construction of commercial contracts has any application in the field of patent construction.

3.15 It should be noted from the provisions of the Protocol, to which I have referred, that it was designed, at least in part, to make clear that an over literal approach to the patent and in particular the claims set out in the patent was not to be adopted. It might well be said that a literal approach had, in the past, found favour in common law countries. However that overly literal approach had been abandoned in the common law world in advance of the adoption of the protocol. In *Catnic Components Ltd v. Hill and Smith Ltd* [1982] RPC 183 at 242-243 Lord Diplock said the following:-

> "My Lords, the proper specification is a unilateral statement by the patentee, in words of his own choosing, addressed to those likely to have a practical interest in the subject matter of his invention (i.e. 'skilled in the art'), by which he informs them what he claims to be the essential features of the new product or process for which the letters patent grant him a monopoly. It is those novel features only that he claims to be essential that constitute the so called 'pith and marrow' of the claim. The patent specification should be given a purposive construction rather than a purely literal one derived from applying to it the kind of meticulous verbal analysis in which lawyers are too often tempted by their trainee to indulge. The question in each case is: whether persons with practical knowledge and experience of the kind of work in which the invention was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee to be an essential requirement of the invention so that any variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked."

3.16 That decision gave rise to what became known as the protocol questions. However, since *Kirin-Amgen*, those questions have no longer had quite the same status. The question in *Kirin-Amgen* concerned the level of generality of the patent concerned. In the course of the speech of Lord Hoffman the true question was stated to be:-

> "What would a person skilled in the art have understood the patentee to have used the language of the claim to mean?"

Anything else, in Lord Hoffman's view, was only guidance directed towards attempting to answer that question.

3.17 In *Kirin-Amgen* Lord Hoffman approved, subject to one modification, the summary given in *Technip France SA's* patent in the following terms:-

> "(a) The first, overarching principle, is that contained in Art. 69 itself. Sometimes I wonder whether people spend more time on the gloss to Art. 69, the Protocol, than to the Article itself, even though it is the Article which is the main governing provision.
>
> (b) Article 69 says that the extent of protection is determined by the terms of the claims. It goes on to say that the description and drawings shall be used to interpret the claims. In short the claims are to be construed in context.
>
> (c) It follows that the claims are to be construed purposively--the inventor's purpose being ascertained from the description and

drawings.

(d) It further follows that the claims must not be construed as if they stood alone--the drawings and description only being used to resolve any ambiguity. The Protocol expressly eschews such a method of construction but to my mind that would be so without the Protocol. Purpose is vital to the construction of claims.

(e) When ascertaining the inventor's purpose, it must be remembered that he may have several purposes depending on the level of generality of his invention. Typically, for instance, an inventor may have one, generally more than one, specific embodiment as well as a generalised concept. It is the latter which matters when construing the claim, particularly the widest claim. Otherwise one is in danger of being unfair to the inventor. I put it this way in *Tickner v Honda Motor Co Ltd* [2002]1 EWHC 8 (Patents) at para. [28]: "The whole approach goes by the sobriquet purposive construction'. You learn the inventor's purpose by understanding his technical contribution from the specification and drawings. You keep that purpose in mind when considering what the terms of the claim mean. You choose a meaning consistent with that purpose--even if that involves a meaning which, acontextually, you would not ascribe to the word or phrase. Of course in this exercise you must also be fair to the patentee--and in particular must not take too narrow a view of his purpose--it is the widest purpose consistent with his teaching which should be used for purposive construction.

(f) Nonetheless purpose is not the be-all and end-all. One is still at the end of the day concerned with the meaning of the language used. Hence the other extreme of the Protocol--a mere guideline--is also ruled out by Art. 69 itself. It is the terms of the claims which delineate the patentee's territory.

(g) It follows that if the patentee has included what is obviously a deliberate limitation in his claims, it must have a meaning. One cannot disregard obviously intentional elements. Hoffmann L.J put it this way in *Société Technique de Pulverisation STEP v Emson Europe Ltd* [1993] R. P. C. at 522: "The well-known principle that patent claims are given a purposive construction does not mean that an integer can be treated as struck out if it does not appear to make any difference to the inventive concept. It may have some other purpose buried in the prior art and even if this is not discernible, the patentee may have had some reason of his own for introducing it."

(h) It also follows that where a patentee has used a word or phrase which, acontextually, might have a particular meaning (narrow or wide) it does not necessarily have that meaning in context. A good example of this is the *Catnic* case itself--"vertical" in context did not mean "geometrically vertical", it meant "vertical enough to do the job" (of supporting the upper horizontal plate). The so-called "Protocol questions" (those formulated by Hoffmann J. in *Drover Corp v Remington Consumer Products Ltd* [1990] F.S.R. 181 at p.189) are of particular value when considering the difference of meaning between a word or phrase out of context and that word or phrase in context. At that point the first two Protocol questions come into play. But once one focuses on the word in context, the Protocol question approach does not resolve the ultimate question--what does the word or phrase actually mean, when construed purposively? That can only be done on the language used, read in context.

(i) It further follows that there is no general "doctrine of equivalents". Any student of patent law knows that various legal systems allow for such a concept, but that none of them can agree what it is or should be. Here is not the place to set forth the myriad versions of such a doctrine. For my part I do not think that Art. 69 itself allows for such a concept--it says the extent of protection shall be determined by the terms of the claims. And so far as I can understand, the French and German versions mean the same thing. Nor can I see how the Protocol can create any such doctrine.

(j) On the other hand purposive construction can lead to the conclusion that a technically trivial or minor difference between an element of a claim and the corresponding element of the alleged infringement nonetheless falls within the meaning of the element when read purposively. This is not because there is a doctrine of equivalents: it is because that is the fair way to read the claim in context.

(k) Finally purposive construction leads one to eschew what Lord Diplock in *Catnic* called (at p.243): "the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge". Pedantry and patents are incompatible. In *Catnic* the rejected "meticulous verbal analysis" was the argument that because the word "horizontal" was qualified by "substantially" whereas "vertical" was not, the latter must mean "geometrically vertical."

The modification adopted by Lord Hoffman is to be found in para. (e).

3.18 However, in the proceedings between these parties in the courts in the United Kingdom, the Court of Appeal (in rejecting the appeal by Ranbaxy against the findings of Pumfrey J. in the English High Court) said as follows:-

> "Lord Diplock said in the Antaios case [1985] AC 191, 201:-
>
> > 'I take this opportunity of re-stating that if detailed semantic and syntactical analysis of words in a commercial contract is going to lead to a conclusion that flouts business commonsense, it must be made to yield to business commonsense.'
>
> Lord Hoffman made clear in *Kirin* at (31) that this applies equally to the construction to patent claims. It applies here."

3.19 Thus, it is argued on behalf of Warner-Lambert, an approach analogous to the business efficacy construction requirements in respect of commercial contracts applies also in the case of the construction of a patent. Counsel for Ranbaxy argues that the Court of Appeal decision in the English proceedings misconstrued the decision of the House of Lords in *Kirin-Amgen* and, in that regard, fell into error. Counsel for Warner-Lambert places reliance on the Court of Appeal decision. The irony of London counsel inviting me to hold that the English Court of Appeal was wrong while Dublin counsel argue that it was right, is not lost on me. However, it is an issue on which I must form on my own view as the proper principles applicable in the construction of an Irish patent and as a matter of Irish law.

3.20 The only real legal issue of substance is, therefore, as to whether, by analogy with commercial contract constructions rules, a business commonsense construction test applies.

3.21 It seems to me that recent developments in a number of jurisdictions and in a number of areas of construction, all betray a common tendency. Very many different forms of document are designed to determine legal rights and obligations. At one end of the spectrum are the laws of the land to be found in the Constitution, Acts of the Oireachtas, and Instruments made with the authority of those Acts. A whole host of other forms of documents govern the legal relations between parties. Contracts are frequently in written form. Unincorporated bodies govern the relations of their members by means of rules, corporate bodies by their Articles of Association. A document such as a patent, as had been seen, defines the extent of the monopoly of the patentee.

3.22 Where questions arise as to the proper construction of a document having legal effect, then it falls to a court to construe it and thus determine its effect on the legal rights and obligations involved. That construction may involve determining the law of the land, the nature of bilateral contractual relations, the obligations or entitlements of a member of unincorporated or corporate bodies or the boundaries of a patentee's monopoly. However it seems to me that the overall principle behind the construction of any document which is intended or is likely to effect legal entitlements and obligations is that it must be construed in the context of its purpose and in a manner which those whose rights and obligations are likely to be effected by it, would understand it.

3.23 The most fundamental aspect of context is the nature of the document itself. One expects an Act of the Oireachtas to be drafted in a particular way and with a considerable amount of care. One would not likely assume there to have been a mistake. Similarly significant commercial contracts, carefully negotiated with the assistance of experienced lawyers, must be assumed to have been properly worked out by those lawyers. A court will not likely assume a mistake in this regard either. However where specialist or technical language is used, a court may require evidence to understand that language in context. In addition a court may need to know the overall context of the circumstances leading to the negotiation of the contract in the first place. This is because the contract should be construed in the way in which a reasonable and informed person entering into a contract of that type would be likely to interpret it. That person will not come to the interpretation of the contract with a blank mind. The contractual negotiations will commence against a particular factual backdrop and the parties will be seeking to advance their commercial interests against that factual back drop.

3.24 The position of the skilled addressee in relation to a patent is, in reality, in my view, no more than a special case of that generality. The equivalent, in a commercial context, of the skilled addressee may be the person who understands the overall context within which the contract is entered into and who is, thus, in a position to interpret properly any terminology used. The skilled addressee also has his counterpart in the bystander by reference to whom implied terms may be found to exist.

3.25 I do not, therefore, see that there is any magical difference between the proper approach to the construction of a patent, on the one hand, or any other document intended to effect legal obligations and entitlements, on the other hand. It is, of course, the case that, by virtue of the provisions of the Act, the protocol of the EPC must be applied in construing any patent. Whatever effect the protocol might have had if applied to the traditional literal approach to construction of legal documents, it does not seem to me that the requirements of the protocol differ materially from the modern purposive approach. Every legal document should be read from the perspective of the type of person likely to be involved with it and have a true interest in what it says. Why, in the commercial field, does, in the words of Lord Diplock, the construction of a commercial contract need to yield to commercial commonsense. The answer is that the overlying assumption is that the parties intended to create a workable business arrangement. If an overly narrow literal construction of the contract leads to a result which does not make business common sense then the reasonable reader (for example, another business person in the field who has a legitimate commercial interest in understanding what the agreement meant), would be likely to read it in a way which gives it business commonsense.

3.26 It is important, of course, to emphasise that the court is not involved, in such a construction process, in rewriting what the parties have themselves agreed. The court is simply interpreting the words which they have used in a manner which makes sense. Even if it is clear that there is an obvious technical error, the court may be unable to correct that error because it may not be possible to tell what the parties would have intended (and thus imply a term) had the parties not made the error concerned in the text.

3.27 It is also important to note that a court is not involved in an exercise of deciding whether one or other side has made a "good bargain", still less in redressing any perceived lack of a good bargain. Commercial entities enter into contracts for a whole range of reasons. Sometimes they make a good deal – sometimes they don't. Provided that the workings of the contract make commercial sense then it is no business of the court to second guess the bargain which the parties have themselves negotiated. The business efficacy requirement only comes into play where either the court is faced with a choice between competing constructions, one of which makes business sense and the other does not, or where there has clearly been a technical error in the drafting of the contract and where it is clear, both from the remainder of the contract and from the general context within which the contract was entered into, what the correct provision should be.

3.28 I see no reason why an analogous principle should not, as identified by the Court of Appeal in the case between these parties in the United Kingdom, have application in the patent field. Counsel for Ranbaxy argues that the only application of a "doesn't make sense" principal is to technological questions. Thus, it is argued, it is permissible to have regard to whether a contended for limitation in the scope of the patent would make technological sense. On that basis, in *Catnic*, the term "vertical" as used in a patent for a lintel, was not found by the court to confine the invention to one using exactly a 90° angle. It was held that the skilled addressee would not read the patent as being so narrowly confined. However it does not seem to me that the principle is confined to purely technological considerations. If, for whatever reason, the skilled addressee would take the view that no rational patentee would have confined him or herself in a particular manner, then the patent should not be construed in a way which a skilled addressee would regard no rational patentee as having intended. It is, however, important to note a limitation on this approach. In considering such a limitation in *Telsonic A.G.'s Patent* [2004] R.P.C. 38, Laddie J. said the following:-

> "One is driven to ask, why the inventor put any limitations at the end of the claim. To that there is no stated or obvious answer. One can only speculate. Perhaps it was prior art. Perhaps it was a mistake. In the circumstances, to adopt the approach in *Catnic*, it would not be apparent to the skilled addressee that the limitations 'cannot have been intended by the patentee'.
>
> Both from the claims and the specification it is apparent that limitations were intended. Alternatively, to use the approach suggested in Merck v. Generics, the addressee could not conclude with reasonable confidence that the Single Bend Rod design was one the patentee wanted to cover."

It is important to emphasise two aspects of the reasoning contained in that passage. Firstly, the limitation with which the court was concerned was clear. Secondly there was nothing in the common general knowledge of the skilled addressee, as applied to the text of the patent, which could have lead the skilled addressee to reach any conclusion as to why the limitation had been included. If, therefore, a limitation is clear, then it may be difficult for the patentee to avoid the limitation.

3.29 Obviously there are differences between the context of a patent and a commercial contract. The first and most obvious is that the patent is designed to be read and understood principally by persons working in the relevant scientific or technical field. Secondly a patent is, at least to a significant extent, a unilateral document, rather than one negotiated between two parties. The patent is unilateral in the sense that it is for the patentee to draft the patent specification and claims in whatever way he wants. There may, of course, be practical limitations. The patentee also knows that if the patent application does not pass muster with the patent office he will not get a patent at all. It is that part of the general context that has lead the courts to assume that the skilled addressee would at least have a broad general knowledge of the basic principles behind patent law See *Kirin-Amgen* at paragraph 78 where it is noted that the skilled addressee must be "assumed to know the basic principles of patentability". The reason for that assumption is that any person attempting to understand a patent has to start from a consideration of what the patent itself is trying to do. It is trying to secure a monopoly but in the context of having to meet the legal requirements imposed under statute by the patent office to the grant of that monopoly. That is the fundamental context within which a patent has to be considered in just the same way as the fundamental context within which a commercial contract has to be construed is that it was designed to create binding and effective commercial relations between the parties.

3.30 Just as it is no part of a court's function to rewrite a commercial contract because the commercial bargain may appear somewhat one sided, so equally it is no part of the role of a court in construing a patent to look at the commercial benefits that the patentee might obtain from it. I do not understand the Court of Appeal to have adopted a principle of that variety. It did not consider that the court should ask itself if the patentee might have done better commercially had he meant X rather than Y and thus assume that the patent should be construed as X because interpreted in that way it would be a "better" patent from the commercial perspective of the patentee.

3.31 It seems to be clear from the judgment of the Court of Appeal in the proceedings between these parties that a different approach was adopted.

3.32 From paragraph 20 of the judgment of Jacob L.J. it is clear that the form of interpretation which should be leaned against is one which "no rational patentee would have intended". There is not, therefore, a principle of construction to the effect that the Court should lean in favour of an interpretation which might be perceived to be more commercially beneficial from the perspective of the patentee. There can, as a number of the authorities have pointed out, be all sorts of reasons why a patentee may choose to limit his claim in one fashion or another. I am, however,

satisfied that, just as a court will lean against the construction of a commercial contract where it can be shown that the construction contended for would lead to a commercial nonsense, so also should a court in construing a patent adopt an analogous approach and lean against a construction for which there is no rational basis from the perspective of the patentee. That is not to say that the court will enter into a detailed analysis of the sort of considerations that might have entered the patentee's mind. The issue of construction is to be addressed from the perspective of the skilled addressee. That skilled addressee must be taken to know what the purpose of the patent is and the basic principles of patent law which would inform any person as to the general way in which a patent application would be formulated. If, from that perspective, a particular construction would immediately seem to the skilled addressee to be irrational, then there seems to me to be no reason in principle why the court should not take that fact into significant account in the construction exercise. I propose approaching the question of construction on that basis. However, before going on to consider the terms of the patent itself, I should briefly touch upon certain aspects of the international litigation between these and connected parties over similar patents.

4. The International Litigation

4.1 I have already touched upon the fact that in proceedings in the United Kingdom between connected companies Ranbaxy failed in both the High Court (Pumfrey J. [2005] E.W.H.C. 2142) and in the Court of Appeal. I have already referred to certain aspects of the judgment of Jacob L.J. in the Court of Appeal.

4.2 In addition the Federal Court of Australia came to a similar conclusion. The judgment of Young J. of the 20th December, 2006 sets out the reason for that conclusion. Furthermore the United States District Court for the district of Delaware and the United States Court of Appeals for the Federal Circuit (an appeal) have come to similar conclusions with the determination of the Appeals Court being on the 2nd August, 2006. Finally, just before these proceedings commenced, the Federal Court of Canada delivered judgment in proceedings in that jurisdiction. The judgment and order of von Finckenstein J. of the 25th January, 2007 sets out the reasons for that determination.

4.3 It is true to state, therefore, that in most of the major jurisdictions within the common law world there has already been a determination on an analogous issue and in each case so far determined the decision has been against Ranbaxy. I accept the point made by counsel on behalf of Ranbaxy that some caution needs to be exercised in relation to over reliance on judgments from other jurisdictions. While the patents with which each of the relevant courts were concerned are, to a very considerable extent, the same, it does appear that there may be at least some minor differences between the respective patents in the respective jurisdictions. Whether any differences are such as should, of themselves, lead to a different construction being placed on the fundamental question as to whether the patent covers only racemic mixtures on the one hand or either enantiomer or any mixture of the enantiomers, on the other hand, is another question. However it is appropriate sound a note of at least some caution deriving from the fact that there are undoubtedly at least some differences in the text of the patents with which the various courts were concerned.

4.4 Secondly, it is important to note that, while the broad scope of patent law has many similarities from one common law country to the next, there are, undoubtedly, some differences in the established approach in the respective jurisdictions. In particular the underlying statutory basis does differ. Ireland and the United Kingdom have, of course, the EPC in common and, as was pointed out by counsel for Ranbaxy, the Act is in very similar terms to the equivalent United Kingdom legislation and is clearly closely modelled on the United Kingdom Patents Act, 1977. This is hardly surprising as both the UK and Ireland are signatories to and have ratified the EPC. It is fair to state that less caution needs, therefore, to be exercised in considering the application of judgments of the Courts of the United Kingdom than other common law countries. In those circumstances it seems to me that, while it would not be appropriate to ignore the jurisprudence of other common law countries, it is the decisions of the United Kingdom courts that require most attention. The broad approach to the construction of patents is, of course, at least similar. Unless there is a material statutory difference or an established variation in the applicable jurisprudence it does seem to me that non United Kingdom common law authorities are also persuasive in this context. However, for the reasons I have set out, caution should be applied and it should not be assumed that all relevant factors are necessary the same.

4.5 Finally, by way of caution, it is also appropriate to note that each case must be determined on the evidence presented to the court concerned. For the reasons which I have already analysed, that evidence should be confined to demonstrating what the knowledge of the skilled addressee would have been as of the priority date. Given that the relevant knowledge is international it would be surprising if there were very significant differences between the conclusions which could properly be arrived at from one country to the next as to what the knowledge of the skilled addressee as of that date would have been. However, the court is, nonetheless, bound by the evidence presented to it. In that context it is worthy of some note that both Professor Clive and Dr. Newton had previously given evidence in some of the other international litigation. Quite an amount of the cross-examination of both witnesses was concerned with what might be reasonably be described as suggestions of nuanced differences between the evidence now being tendered and that given on previous occasions. I have to say that such an eventuality, far from being a matter of criticism, is to be expected. The precise focus of the issues upon which a case may come to turn will undoubtedly crystallise in the course of litigation. If a second set of litigation, of an almost identical variety, is then conducted with the same expert witnesses, it is hardly surprising that the legal advisors of the parties and those witnesses will focus more closely on what have turned out to be the key issues. It should not be assumed that the evidence given on the first occasion is some form of sacret text which cannot be altered. There are doubtless things that were not said because questions were not asked or issues did not arise in precisely the same way. The fact that issues may arise in a more focused way in a second or subsequent piece of litigation between the same parties is almost certain to lead to some evolution in the evidence given. That is not to say that a court would readily accept a significant alternation in the evidence given by a witness. It would require a very telling explanation to justify a witness significantly altering evidence previously given as to the state of knowledge of the skilled addressee. However, a greater focus, within that evidence, on specific questions which may not have been explored as fully in previous litigation is likely, legitimately, to lead to some nuanced evolution of the evidence given. I did not see the evidence given by either Professor Clive or Dr Newton as varying, beyond that extent, from the evidence which they had previously given. To the extent that either of the experts evidence was criticised in that regard, I reject that criticism.

4.6 Finally, it is important that I deal with the question of the status of other litigation. It is important not to confuse two difference concepts. Appropriate decisions from other common law countries are, of course, afforded persuasive status by the courts in this jurisdiction and, indeed, by the courts in many common law countries. That status is wholly independent of any connection between the litigation in which the decision was handed down on the one hand and the litigation under consideration on the other hand. What is afforded the status of persuasive authority are the legal principles to be derived from the decision rather than the decision itself.

4.7 An entirely separate consideration has to be given to the result of foreign litigation which touches upon the same actual matters (rather than the same legal principles). The principle of the comity of courts requires that the courts in one jurisdiction should not likely depart from a decision on the same issue made by a court of competent jurisdiction in another country which had to deal with that issue as part of litigation properly under its consideration. Thus, for example, where the courts in one jurisdiction have interpreted a contract in an particular way and where the same contract comes to be interpreted, in a separate dispute between the same or similar parties, in the courts of another jurisdiction, then the comity of courts requires that the interpretation of the contract in the second proceedings should not lightly depart from the interpretation given to the same contract in the first proceedings.

4.8 This latter principle, it seems to me, ought also apply, though obviously to a more limited extent, where the issue, while not identical, is very similar. For those reasons it seems to me to be appropriate, subject to the caveats relating to differences in statutory law, jurisprudence, the patents themselves, and the evidence which I have already identified, to pay appropriate regard to the international decisions in the related cases.

4.9 However it is also important not to lose sight of the fact that the international decisions in this case (and in particular the decisions taken by the courts of the United Kingdom which derive from an almost identical statutory regime and analogous jurisprudence) have also the status, as to their principles, of persuasive authority. If the decision of the United Kingdom Court of Appeal in the proceedings between these parties had been between wholly separate parties then, nonetheless, the comments of Jacob L. J. on "business common sense" would be a persuasive authority in

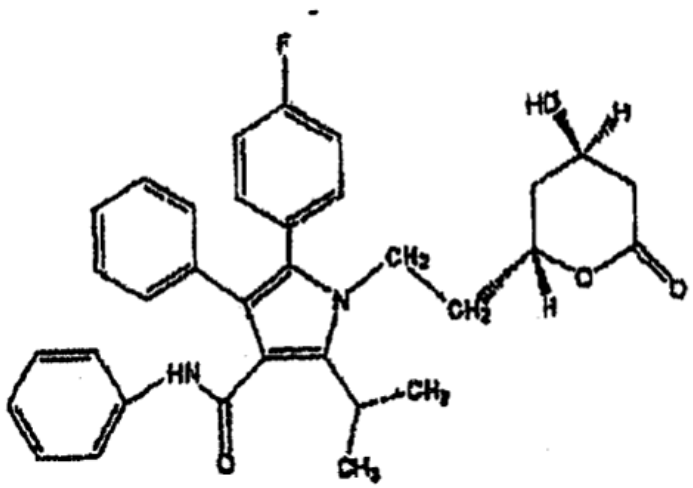
this jurisdiction. It would, of course, be open to any party to suggest that this court should not be "persuaded" because the case was wrongly decided. Such a course of action is always open to any party. However, that decision, like any decision of the Court of Appeal in the United Kingdom in this field, is likely to be regarded as persuasive by our courts in the absence of a good reason for not so doing. For the reasons which I have already analysed I am satisfied that the decision of the United Kingdom Court of Appeal in the proceedings between these parties is persuasive as to the principles to the be applied and I propose following it.

4.10 In addition, and subject to the caveats which I have identified, I also propose to have regard, where appropriate, to the views expressed on identical issues in the other international cases involving these parties.

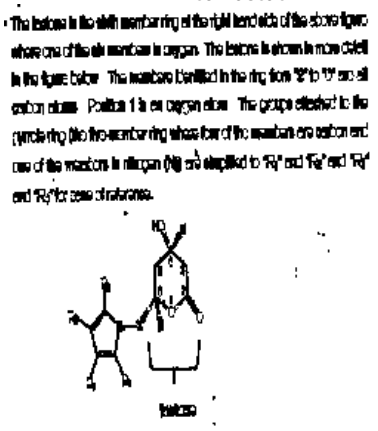
4.11 Against that legal background I now propose to turn to the patent itself.

5. The Patent

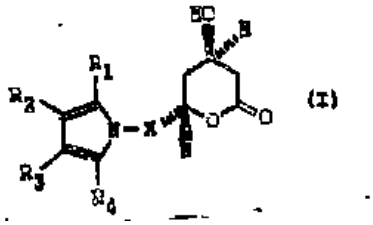
5.1 It was agreed by both sides that stereochemistry, while an essential part of the understanding necessary to interpret the patent, was not central to the patent itself. Stereochemistry is the general background. The series of papers produced by Stokker and his associates in the immediate run-up to the priority date are the specific background. Atorvastatin is a member of a class of drugs known by the generic term "statin". The drawing below depicts a form of atorvastatin known as the lactone form



Atorvastatin



5.2 The patent itself discloses a class of compounds that are said to have the ability to inhibit HMG-CoA reductase which is the rate controlling enzyme involved in biosynthesis of cholesterol. The structural formula for the class of compounds concerned is set out diagrammatically in a number of places in the specification including claim 1 in the following form:-



wherein x is -CH2, - CH2 CH2, - CH2 CH2 CH2 or – CH2 CH(CH3)

5.3 It is, in particular, the proper interpretation of structural formula 1 that is at the heart of the dispute between the parties in this case. As of the priority date statins were well known as potential cholesterol lowering medicines. The configuration of two important statins (mevinolin and compactin) were known and it had already been demonstrated that, in their case, it was the "trans" isomers that had potent biological activity.

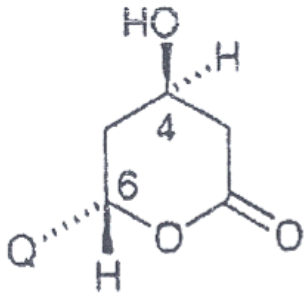
5.4 The molecule depicted in structural formula 1 has two co called heterocyclic rings. The five membered left hand ring is known as a pyrrole ring and includes a number of possible substituents. The right hand ring is known as a lactone ring and has two substituents. It will be seen that theses two substituents (being the OH group shown at the top of the ring and the X which links to the pyrrole ring at the bottom) are depicted as being on opposite sides of the plane of the page and are thus in a "trans" relationship.

5.5 It is important, in that context, to note the express provisions set out on p. 6 lines 16-24 of the patent which states as follows:

> "The compounds of structural formulae 1 above possess two asymmetric carbon centres, one at the 4-hydroxy position of the pyran-2-one ring, and the other at the 6-position of the pyran-2-one ring where the alkylpyrrole ground is attached. This asymmetry gives rise to four possible isomers, two of which are the R-cis- and S-cis-isomers and the other two of which are the R-trans- and S-trans-isomers. This invention contemplates only the trans-form of the compounds of formula 1 above."

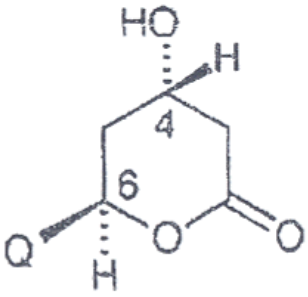
5.6 The judgment of the English Court of Appeal set out a figure which shows the four possible isomers in the following way:-

The Stereoisomeric Consequences of two chiral centres at Positions 4 & 6



R,R or
4R,6R or
4R-trans or
R (R*,R*)

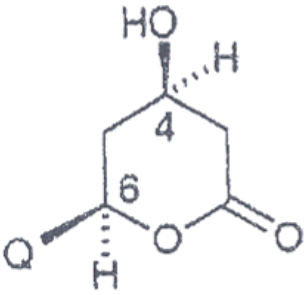
A



S,S or
4S,6S or
4S-trans or
S (R*,R*)

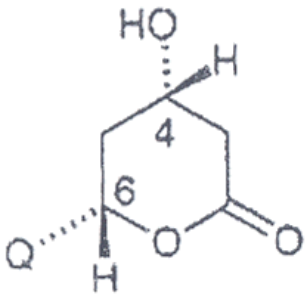
B

- A&B are non-superimposible mirror images I e a pair of enantiomers
- Both A&B are <u>trans</u> - (i e the groups OH and Q at positions 4 and 6 are arranged with one above and



R,S or
4R,6S or
4R-cis or
R(R*,S*)

C



S,R or
4S,6R or
4S-cis or
S(R*,S*)

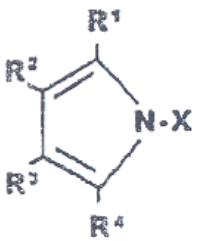
D

- C&D are also <u>a pair of enantiomers</u>
- Both C&D are <u>cis</u> - (i e the groups OH and Q at positions 4 and 6 are arranged with

Mirror plane

In each case:

Q=



5.7 The other key element of the patent, for the purposes of its construction, is to be found in a series of pages depicting what are described as reaction sequence I and reaction sequence II. As the patent itself says in a passage starting on line 36 at p. 7:-

> "The compounds of this invention are prepared by the general reaction scheme outlined in reaction sequence I which takes advantage of the chemistry of mesionic compounds of the type described originally by R. Huisgen."

There then follows a description by reference to a depiction of how the compounds are to be prepared. The end of the sequence (which is to be found at the bottom left of p. 11) is depicted in exactly the same way as structural formula 1.

5.8 A central plank of Ranbaxy's claim stems from the depiction on p. 11 to which I have referred. All of the expert evidence agrees that the sequence depicted and described as culminating in the compound shown at the bottom left on p. 11 gives rise to a racemic mixture.

5.9 While it was well known to experts in the field at that time that it was possible to break down the racemic mixture into its individual enantiomers, it is common case that the reaction sequence as depicted on the relevant pages ends with a racemic mixture and no further sequences, whether by description or depiction, are given which show that racemic mixture being further broken down into the individual enantiomers or non racemic mixtures.

5.10 Placing reliance on the fact that the depiction set out on p. 11 is identical to the depiction set out in claim 1, Ranbaxy argues that claim 1 must also, in those circumstances, be taken to represent a racemate and that the boundary of the patent is, therefore, confined to a racemate and not to the individual enantiomers, or non racemic mixtures.

5.11 There is clearly an argument to that effect. It is undoubtedly the case that the two depictions (that on p. 11 and that set out in claim 1) are identical. It follows that there is an argument to the effect that they must be taken to mean the same thing. Given that the compound that would be produced by the reaction sequence is, it is common case, a racemate, then there clearly is an argument to the effect that the depiction in claim 1 must also be a racemate. However, it does not seem to me that the issue is quite as clear cut as that. Firstly the very approach recommended in *Kirin-Amgen* is to avoid an over semantic approach to the construction of patent documents on the basis that they are designed to be read by experts in the field rather than lawyers. A lawyer would, undoubtedly, be inclined to the view that the presence of a word or phrase (or indeed a depiction) in two separate parts of a single legal document must be intended to mean the same thing. However the depictions have to be seen in context.

5.12 The most common everyday example of two objects which are the mirror image of each other can be found in the left and right hands of any person. Provided that one can tell whether one is looking at the front or back of a hand, and is able to identify the thumb, it will always be possible to tell whether a hand is left or right. However the fact that a (say) right hand is depicted does not necessarily mean that the author of the depiction concerned intended to show a right hand to the exclusion of a left hand. It depends on context. The question is as to whether, in context, the use of the depiction set out in structural formula 1 would be understood, by a skilled addressee, to mean only the racemate or whether it would be understood to include both enantiomers and any mixture of the two.

5.13 Warner-Lambert places particular reliance on the passage from the text of the patent at p. 6 which I have already quoted. There is no doubt but that that passage expressly excludes from the scope of the patent the "cis" compounds and thus excludes examples C and D from the four possible compounds taken from the example borrowed from the English Court of Appeal. The exclusion of the cis form comes immediately after the patent expressly sets out the four possible isomers. In that context, Warner-Lambert argues that having noted the four isomers, and having excluded two of them, the patent necessarily conveys an intention to claim the other two (that is to say both of the "trans" isomers). Warner-Lambert argues that a skilled addressee, in looking at structural formula 1, and in seeking to construe that formula in the context of the patent as a whole, would necessarily have had regard to what is said on p. 6 and would therefore see structural formula 1 as representing either of the "trans" isomers and thereby including any possible mixture of same.

5.14 Apart from the text of the patent itself both sides also explored the general knowledge available as of the priority date in aid of their contentions. As pointed out earlier there was a significant body of knowledge which made it highly likely that the R-trans enantiomer would have most, if not all, of the beneficial potency. There was some dispute between the experts as to whether, at the relevant time, it would have been clear that there was no potency at all in the S-trans enantiomer. I am not satisfied that the evidence goes that far. However it is common case that the skilled addressee would have read the patent with the knowledge that the level of potency available from the S-trans enantiomer would have been likely to be extremely limited.

5.15 To some extent both sides rely on this fact as part of their argument.

5.16 Ranbaxy suggest that the absence of any significant potency in the S-trans enantiomer would lead the skilled addressee to take the view that Warner-Lambert could not have been seeking a patent involving the S-trans enantiomer not least because it would not seem to deliver the claimed beneficial effects of the patent.

5.17 On the other hand Warner-Lambert suggest that the skilled addressee could not have found any basis upon which Warner-Lambert would have wished to patent only the racemic mixture when it was known that by far the greater preponderance of the potency was to be found in the R-trans enantiomer.

5.18 The weight to be attached to those arguments, it seems to me, depends to some extent on the legal issue which I have already addressed. For the reasons which I have set out I am satisfied that I am entitled to have regard to whether, in the words of Jacobs L.J, "no rational patentee would have intended" that the claim should be confined in a particular manner contended for. It is important to emphasise that it is not for the court to attempt to second guess what might or might not have been the reasons for a patentee formulating a patent application in a particular way. If there is a basis upon which a patentee might have wished to construct the patent application in a particular way (even though, and perhaps with the benefit of hindsight, it might turn out that he would have been much better advised to have done it in a different way) then that is not a matter to which the court can pay any regard. Nor, of course, can the court rewrite the patent. Parties are fixed with the terms used in the patent application. However where there is difficulty in construction it is, in my view, permissible for the court to have regard to the question of whether any rational patentee would have constructed a patent application in the manner contended for as one of the possible constructions of the patent document.

5.19 Some evidence was addressed to both the Ranbaxy and Warner-Lambert arguments under this heading.

5.20 The Ranbaxy argument is predicated on the fact that the skilled addressee would have known that the S-trans enantiomer was of little or no potency and thus or little or no use to the patentee. Why then, it is rhetorically asked, would it be included in the patent at all. However Dr. Newton gave evidence concerning the range of additional matters which are relevant to the conversion of a potentially beneficial compound into a successful drug. He described them as stability, effective absorption, avoidance of first pass metabolism non-inhibition of liver enzymes, solubility, non-accumulation, selectivity, non-toxicity and duration of action. It was suggested in Ranbaxy's closing submission that Dr. Newton's evidence in that regard was an attempt to suggest that those elements might be part of the patent. I did not understand his evidence in that way. Dr. Newton was asked to comment on whether there might be any point in patenting the S-trans enantiomer when it was known that it would have little or no potency. He made the point that there are many steps between the identification of the potent compound and its emergence as a usable medicinal product.

5.21 It is this aspect of the science that Dr. Newton, with his practical experience as a medicinal chemist, was particularly well qualified to comment on. I am, therefore, satisfied that, applying the state of general knowledge as of the priority date, it was by no means clear that the

presence of the S-trans enantiomer in an appropriate mixture might not have formed a useful part of any such process. In addition it was not clear, as of that time, that whatever role might be played (if any) by the S-trans enantiomer in the final medicinal product might not give at least some marginal benefit, in terms of potency, from the presence of the S-trans enantiomer. I am not, therefore, satisfied that a skilled addressee, as of the priority date, would have formed the view that there was no point whatsoever in seeking to include the S-trans enantiomer within the patent. While the skilled addressee would undoubtedly have been of the view that it was highly unlikely that the S-trans enantiomer would have a potency of any great value, it does not follow that it would be of no value particularly when there might be good reasons connected with the creation of practical medicines as to why some of the S-trans enantiomer might have to be utilised. The S-trans enantiomer could also, in that context, have played a role in delivering the promise of the patent as a whole to deliver improved treatment of cholesterol.

5.22 Insofar as Warner-Lambert's argument on the "irrationality" of seeking a patent for a racemic mixture when it was known that most of the potency resided in the R-trans enantiomer is concerned, Ranbaxy seeks to place reliance on the possibility that obtaining a patent for a racemic mixture might allow the patentee to obtain a further and later patent for the potent or R-trans enantiomer and thus extend the practical life of the monopoly attaching to the invention. I am not persuaded that the skilled addressee would take that view. The skilled addressee would know that the vast preponderance of the potency would lie in the R-trans enantiomer. In my view a skilled addressee would not see a rational basis for a patentee excluding itself from having a patent in that R-trans enantiomer. It is, I think, important to describe the argument in the way in which I have just done. While Ranbaxy's argument describes the patent as being one which is confined to the racemic mixture it is, of course, a necessary consequence of that argument, if it be correct, that the patent excludes any monopoly in the R-trans enantiomer save when it is present in a racemic mixture. I am not satisfied that a skilled addressee would see that as rational in the context of the knowledge which that skilled addressee would undoubtedly have had to the effect that virtually all of the potency of the compound was present in the R-trans enantiomer.

5.23 I am, therefore, satisfied that the context would cause a skilled addressee to lean in favour of a construction which allowed for an effective monopoly of the R-trans enantiomer. In addition, I am not satisfied that the skilled addressee would regard a construction which also included in S-trans enantiomer as being irrational. This is not, in my view, a case where the limitation is clear (see paragraph 3.28 above). The very issue between the parties is as to whether the limitation is there at all. If it were clear that the claims related only to a racemate (for example if structural formula 1 was described in express terms as a racemate or by reference to a formula which had a symbol such as " ±" which could only be taken to denote a racemate) then different considerations might well apply. In those circumstances there would be a clear limitation. The extent to which that limitation could, if at all and as a matter of construction, be disregarded would be limited. However, here I am concerned not with a case of a clear limitation but rather a question of construction as to whether the limitation is there in the first place. The issue is as to whether the proper construction of structural formula 1 contains a limitation requiring that it be confined to a racemate. It is in those circumstances that, in my view, the Court of Appeal in the proceedings between these parties in the United Kingdom came to apply a "no rational patentee" test. The test was applied in determining whether the limitation was there in the first place rather than as a means of attempting to get around a clearly existing limitation.

5.24 In those circumstances and against that background is there anything in the text of the patent which would force the skilled addressee to come to a different view? I am not satisfied that there is. I place particular emphasis on the passage at p. 6 which, it seems to me, identifies four isomers and expressly excludes two. Without applying a legalistic approach to that formulation it seems to me that a natural reading of it leads to the conclusion that the two isomers not excluded are the isomers in respect of which the patent is going to make its claim. They are, of course, the two separate enantiomers of the trans form that is to say the R-trans and S-trans.

5.25 When one comes to the depiction in structural formula 1 it seems to me that the skilled addressee would be more than well enough aware that there can be a lack of precision in such depictions. The skilled addressee would not, in my view, adopt what seems to me to be an overly legalistic approach to construction in assuming that the depiction set out in structural formula 1 necessarily meant exactly the same thing as the depiction set out as the end process of reaction sequence 2. They are different in context. The reaction sequence is a description of how one actually goes about creating the compound. Structural formula 1 is the compound in respect of which the claim is to be made. There does not seem to me to be any reason in principle why those depictions should not have at least different shades of meaning deriving from the different context in which they appear. When depicted it would seem unlikely that chemists would actually use both enantiomers to describe a racemate. This would involve drawing both molecules when, as a matter of practicality, the second enantiomer can be definitively determined by the application of a mirror image to the first. In those circumstances the skilled addressee would not, in my view, place over emphasis on the precise depiction in structural formula 1. When he or she came to look at structural formula 1 it would be in the context of what had already been said on p. 6. In those circumstances it seems to me that the skilled addressee would be likely to view structural formula 1 as representing either or both enantiomers and in any mixture. There is nothing, therefore, in my view, in the text of the patent which would lead the skilled addressee to move away from the approach which I have already identified.

5.26 One further part of the text of the patent itself seems to me to be of relevance to the construction issue with which I am faced. In addition to making a claim in respect of structural formula 1 (to which I have referred in detail), the claims section of the patent describes a number of different specific compounds in respect of which separate claims are made and which are stated to come within the general class of compounds defined by structural formula 1. It will be noted that structural formula 1 allows for a number of possible variations. The additional claims consist of specific examples within the overall compass of structural formula 1. I note three in particular being Claims 3, 4 and 5 which appear in the following form.

> "3. A compound as defined by Claim 1 having the name trans-(±)-5-(4-fluorophenyl)-2-(1-methylethyl)-N,4-diphenyl-1-(2-(tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl)ethyl)-1H-pyrrole-3-carboxamide.
>
> 4. A compound as defined by Claim 1 having the name trans-2-(4-fluorophenyl)-N,4-diphenyl-1-(2-(tetrahyrdo-4-hydroxy-6-oxo-2H-pyran-2-yl)ethyl)-5-trifluoromethyl-1H-pyrrole-3-carboxamide.
>
> 5. A compound as defined by Claim 1 having the name trans-5-(4-fluorophenyl)-N,4-diphenyl-1-(2-(tetrahydro-4- hydroxyl-6-oxo-2H-pyran-2-yl)ethyl)-2-trifluoromethyl-1H-pyrrole-3-carboxamide."

5.27 Nothing turns, for the purposes of this case, on the general content of those claims. However it will be noted that in Claim 3, immediately after the word trans- there appears in brackets a "±". No such symbol appears in Claims 4 and 5. It will be recalled (from para. 2.7 above) that a racemic mixture is frequently labelled "±". Thus, on a strict reading of the compounds specified at paras. 3 4 and 5, it would appear that the compound specified at para. 3 is expressly described as a racemic mixture, while the compounds specified at paras. 4 and 5 are not so described. Nor are the compounds specified at paras. 4 and 5 designated (by the presence of a "+" or a "-") as being specifically one or other an enantiomer.

5.28 None of the expert witnesses called suggested that a skilled addressee would have attached, in the context of the patent, any significant meaning to the presence of the "±" in compound 3 and the absence of that or any other designation in compounds 4 and 5. None of the experts could point to any conceivable basis for claiming a racemate in compound 3 but not a racemate in respect of compounds 4 and 5. This fact simply confirms to me that a skilled addressee will not approach the reading of chemical formulae in the same way as a lawyer might approach the reading of the text of a contract. It also shows that the presence or otherwise of such symbols may be imprecise and should not, therefore, give rise to over interpretation. The fact that such symbols are, apparently randomly, present or absent in some of the claims emphasises that it is inappropriate to seek to determine whether a particular description may be said to amount to either an enantiomer, a racemic mixture, or any other mixture, by reference to a literal approach to what appears on the page. In context, a skilled addressee would not, it seems to me, have paid any attention to the presence or otherwise of the "±" in those claims. He would not have done so because, from the context, it would not have appeared to him to be material. In similar fashion I am not satisfied that the skilled addressee, in interpreting structural formula 1, would have taken a literal approach to the comparison between the compound described in structural formula 1 and the identically depicted formula

which appears at the end of reaction sequence II.

5.29 While not, of itself, therefore, of particular importance in the construction of the contested aspects of this patent, it is, in my view, illustrative of the approach which would be adopted by a skilled addressee and confirms the views which I have already expressed concerning the proper interpretation of structural formula 1.

5.30 In all the circumstances it seems to me that the skilled addressee would have read structural formula 1 in the claim in the patent in the manner contended for by Warner-Lambert.

6. Conclusion

6.1 In those circumstances it seems to me that the proper construction of the patent is as contended for by Warner-Lambert. It includes both individual enantiomers and also any mixture thereof. That being the case it necessarily follows that Rambaxy's potentially competing product (being based on the R-trans enantiomer) infringes the patent.

6.2 It therefore follows that Ranbaxy are not entitled to the declaration sought.

6.3 I should not finish this judgment without expressing my personal heartfelt thanks to Professor Dervilla Donnelly who has acted as assessor throughout the proceedings. From the beginning she has made the understanding of an undoubtedly difficult and complex area as simple as possible. I trust that the underlying scientific statements of fact contained in this judgment are correct. If they are then it is, in no small measure due to Professor Donnelly. If they are not then I have to accept that, despite her best efforts, I have not come to a sufficient understanding of the underlying science.